

U.S. Department of Energy

Washington, D.C.

ORDER

DOE 5700.6C

8-21-91

SUBJECT: QUALITY ASSURANCE

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1. PURPOSE. To establish quality assurance requirements for the Department of Energy (DOE).
 2. CANCELLATION. DOE 5700.6B, QUALITY ASSURANCE, of 9-23-86
 3. SCOPE - The provisions of this Order apply to the work performed by all Departmental Elements and management and operating (M&O) contractors as provided by law and/or contract and as implemented by the Department's Contracting Officer. If conflicts between this and other Departmental Orders exist, the quality assurance requirements of DOE 5700.6C take precedent.
 4. EXEMPTIONS. Specifically excluded from this Order is:
 - a. Work associated with nuclear weapons administered by the Assistant Secretary for Defense Programs. (Work associated with the design, construction, fabrication, operations, maintenance, decommissioning, and decontamination of facilities and equipment used to produce weapons are not excluded from this Order. Appropriate attention shall be given to the weapons component and production facility interfaces.)
 - b. Work administered by the Energy Information Administration.
 - c. Work conducted under the Naval Nuclear Propulsion Program (subparagraph 10g).
 - d. Work licensed by the U.S. Nuclear Regulatory Commission (NRC) or an NRC Agreement State and subject to the quality assurance requirements of that agency.
 - e. Research and development work results which undergo peer review for publication.
 5. REFERENCES. The following references are provided for general information.
 - a. DOE 1324.2A, RECORDS DISPOSITION, of 9-13-88, which defines Federal records and the requirements for their maintenance and retention/disposition.

Distribution:
All Departmental Elements

Initiated by:
Office of Nuclear Energy &
Office of Environment,
Safety & Health.

- b. DOE 2030.4A, REPORTING FRAUD, WASTE, AND ABUSE TO THE OFFICE OF INSPECTOR GENERAL, of 3-19-91, which establishes policies and procedures for reporting fraud, waste, and abuse to the Department of Energy's Office of the Inspector General (IG).
- c. DOE 4330.4A, MAINTENANCE MANAGEMENT PROGRAM, of 10-17-90, which provides general policy and objectives for the establishment of programs for the management and performance of cost-effective maintenance and repair of DOE property, including facilities.
- d. DOE 4700.1, PROJECT MANAGEMENT SYSTEM, of 3-06-87, which provides the principles and requirements governing the development, approval, and execution of DOE's outlay program acquisitions as embodied within the project management system.
- e. DOE 5480.1B, ENVIRONMENT, SAFETY, AND HEALTH PROGRAM FOR DEPARTMENT OPERATIONS, of 9-23-86, which sets forth responsibilities and requirements for the program.
- f. DOE 5480.4, ENVIRONMENT, SAFETY, AND HEALTH PROTECTION STANDARDS, of 5-15-84, which specifies the application of mandatory environmental protection, safety, and health protection (ES&H) standards to DOE operations.
- g. DOE 5480.19, CONDUCT OF OPERATIONS, of 7-9-90, which establishes requirements for conduct of operations at DOE facilities to ensure acceptable operations, provide for continuing improvements in operations, and ensure the maintenance of acceptable margins of safety.
- h. Standards which provide additional interpretive guidance for the development and implementation of quality assurance programs, including the following:
 - (1) American Society of Mechanical Engineers (ASME)/NQA-1, Quality Assurance Program Requirements for Nuclear Facilities,
 - (2) ASME/NQA-2, Quality Assurance Requirements for Nuclear Facility Applications,
 - (3) ASME/NQA-3, Quality Assurance Program Requirements for the Collection of Scientific and Technical Information for site Characterization of High-Level Nuclear Waste Repositories,
 - (4) International Atomic Energy Agency (IAEA) International Nuclear Safety Advisory Group's Safety Series No. 75-INSAG-3, Basic Safety Principles for Nuclear Power Plants, and
 - (5) International Standard for Standardization (ISO) 9000, Quality Management and Quality Assurance Standards- Guidelines for Selection and Use.

- i. Environmental Protection Agency (EPA) guidance documents that apply to environmental protection and/or remediation, including the following.
 - (1) QAMS 004, Guidelines and Specifications for Preparing QA Program Plans,
 - (2) QAMS 005, Interim Guidelines and Specifications for Preparing QA Project Plans,
 - (3) Chapter 1 of SW-846, Test Methods for Evaluating Solid Wastes,
 - (4) EPA 540, Data Quality Objectives for Remedial Response Activities, and
 - (5) EPA 530, Technical Guidance Document: Construction QA for Land Disposal Facilities.
- j. American Society for Testing and Materials (ASTM) standards, including ASTM C1009, Establishing a QA Program for Analytical Chemistry Laboratories Within the Nuclear Industry.

6. DEFINITIONS.

- a. Assessment/Verification. The act of reviewing, inspecting, testing checking, conducting surveillances, auditing, or otherwise determining and documenting whether items, processes, or services meet specified requirements. The terms assessment and verification, as used in DOE 5700.6C, are synonymous; their use is determined by who is performing the work. Assessments are performed by or for senior management. Verifications are performed by the line organization.
- b. Item. An all-inclusive term used in place of any of the following: appurtenance, facility, sample, assembly, component, equipment, material, module, part, structure, subassembly, subsystem, system, unit, documented concepts or data.
- c. Process. A series of actions that achieves an end or result.
- d. Program Secretarial Officer (PSO). The heads of DOE offices with responsibility for specific facilities. These include the Assistant Secretaries for Conservation and Renewable Energy; Nuclear Energy; Defense Programs; and Fossil Energy and the Directors of the Offices of the Energy Research; Civilian Radioactive Waste Management; Environmental Restoration and Waste Management; and New Production Reactors.
- e. Quality. The degree to which an item or process meets or exceeds the user's requirements and expectations.
- f. Quality Assurance. Actions that provide confidence that quality is achieved.

- g. Quality Assurance Program. The overall program established by an organization to implement the requirements of this Order. The Program assigns responsibilities and authorities, defines policies and requirements, and provides for the performance and assessment of work.
- h. Service. The performance of work, such as design, fabrication, inspection, nondestructive examination, repair, or installation.
- i. Senior Management. The manager or managers responsible for mission accomplishment and overall operations. For the DOE, the DOE PSOs and Field Office Managers are responsible for mission accomplishment and overall operations. For DOE M&O contractors, the General Manager or similar top position is responsible for mission accomplishment and overall performance in accordance with the requirements of their contracts or other agreements.
- j. Work. Process of performing a defined task or activity; for example, research and development, operations, maintenance and repair, administration, software development and use, inspection, safeguards and security, data collection, and analysis.

7. POLICY. It is DOE policy to establish quality assurance requirements to ensure that risks and environmental impacts are minimized and that safety, reliability, and performance are maximized through the application of effective management systems commensurate with the risks posed by the facility and its work. This Order implements the policy of the Department to ensure that quality assurance requirements are clearly specified for the broad spectrum of work performed by DOE and its contractors, including safeguards and security.

8. OBJECTIVES. DOE's objectives are to ensure the following:

- a. That senior management provides planning, organization, direction, control, and support to achieve the organization's objectives;
- b. That the line organization achieves quality; and
- c. That overall performance is reviewed and evaluated using a rigorous assessment process.

9. REQUIREMENTS.

a. General.

- (1) Senior management shall be responsible for Quality Assurance Program (QAP) implementation, assessment, and improvement. Departmental Elements and M&O contractors shall develop their QAPs by applying the quality assurance criteria specified in subparagraph 9b. The quality assurance program shall include a discussion of how the criteria will be satisfied taking into consideration the risk associated with the work. Appropriate standards shall be used, wherever applicable, to develop and implement QAPs.

- (2) Guidance for developing and implementing QAPs is provided in Attachment I. This guidance may not be appropriate in its entirety for application to every type of work. Additional Implementation Guides, such as for research and development work, will be developed, and after approval, be incorporated into the provisions of this Order.
- (3) Contractors shall obtain DOE approval of new QAPs prior to commencing work. Contractors working to existing quality assurance programs shall ensure that their QAPs meet the requirements of this Order and shall re-submit their QAPs, together with an implementation plan, to the Lead Program Secretarial Officers (PSOs) for approval within 180 days after this Order becomes effective. Quality assurance programs shall be regarded as approved by DOE 180 days after submittal, including any modifications which have been made or directed by DOE during this period, or receipt of a letter, whichever occurs first.
- (4) DOE contractors may, at any time, make changes to their DOE- approved QAPs. Changes made over the previous year to DOE- approved QAPs shall be submitted annually to the Lead PSO for review. All changes shall be regarded as approved by DOE 90 days after submittal, including any modifications which have been made or directed by DOE during this period, or receipt of a letter, whichever occurs first. The submittals shall identify the changes, the pages affected, the reason for the changes, and the basis for concluding that the revised program continue ,to satisfy the requirements of this Order. Changes made to correct spelling, punctuation, or other editorial items do not require explanation.
- (5) Assessments of the DOE and contractor work shall be conducted based on DOE-approved quality assurance program.
- (6) Programs, guides, and policies which implement this Order shall meet the requirements of DOE 1324.2A. (The Records and Reports Branch, AD-241.1, is available for any needed assistance regarding records ,management.)

b. Quality Assurance Criteria.

- (1) Management.
 - (a) Criterion 1--program. Organizations shall develop, implement, and maintain a written Quality Assurance Program. The QAP shall describe the organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing adequacy of work. The QAP shall describe the management system, including planning, scheduling, and cost control considerations.

- (b) Criterion 2--Personnel Training and Qualification. Personnel shall be trained and qualified to ensure they are capable of performing their assigned work. Personnel shall be provided continuing training to ensure that job proficiency is maintained.
 - (c) Criterion 3--Quality Improvement. The organization shall establish and implement processes to detect and prevent quality problems and to ensure quality improvement. Items and processes that do not meet established requirements shall be identified, controlled, and corrected. Correction shall include identifying the causes of problems and preventing recurrence. Item reliability, process implementation, and other quality-related information shall be reviewed and the data analyzed to identify items and processes needing improvement.
 - (d) Criterion 4--Documents and Records. Documents shall be prepared, reviewed, approved, issued, used, and revised to prescribe processes, specify requirements, or establish design. Records shall be specified, prepared, reviewed, approved, and maintained.
- (2) Performance.
- (a) Criterion 5--Work Processes. Work shall be performed to established technical standards and administrative controls. Work shall be performed under controlled conditions using approved instructions, procedures, or other appropriate means. Items shall be identified and controlled to ensure their proper use. Items shall be maintained to prevent their damage, loss, or deterioration. Equipment used for process monitoring or data collection shall be calibrated and maintained.
 - (b) Criterion 6--Design. Items and processes shall be designed using sound engineering/scientific principles and appropriate standards. Design work, including changes, shall incorporate applicable requirements and design bases. Design interfaces shall be identified and controlled. The adequacy of design products shall be verified or validated by individuals or groups other than those who performed the work. Verification and validation work shall be completed before approval and implementation of the design.
 - (c) Criterion 7--Procurement. The organization shall ensure that procured items and services meet established requirements and perform as specified. Prospective suppliers shall be evaluated and selected on the basis of specified criteria. The organization shall verify that approved suppliers can continue to provide acceptable items and services.

- (d) Criterion 8--Inspection and Acceptance Testing. Inspection and acceptance testing of specified items and processes shall be conducted using established acceptance and performance criteria. Equipment used for inspections and tests shall be calibrated and maintained.

(3) Assessment.

- (a) Criterion 9--Management Assessment. Management at all levels shall periodically assess the integrated quality assurance program and its performance. Problems that hinder the organization from achieving its objectives shall be identified and corrected.
- (b) Criterion 10 - Independent Assessment. Planned and periodic independent assessments shall be conducted to measure item quality and process effectiveness and to promote improvement. The organization performing independent assessments shall have sufficient authority and freedom from the line organization to carry out its responsibilities. Persons conducting independent assessments shall be technically qualified and knowledgeable in the areas assessed.

10. RESPONSIBILITIES AND AUTHORITIES.

- a. Lead Program Secretarial Officers have the responsibility to ensure that the requirements of this Order are implemented. Additionally, they have the following responsibilities:
 - (1) Ensure that DOE Field Offices and contractors to which this Order applies implement the requirements in Paragraph 9, as applicable;
 - (2) Provide program and project direction and resources for work within their purview;
 - (3) Review and approve quality assurance programs and changes thereto within their purview;
 - (4) Assess quality assurance program adequacy and implementation;
 - (5) For nuclear work, provide the Assistant Secretary for Nuclear Energy (NE-1) with recommendations for additions or revisions to nuclear quality assurance standards, guides, and codes; and for non-nuclear work, provide similar recommendations to the Assistant Secretary for Environment, Safety and Health (EH-1);
 - (6) Ensure that Field Office Managers comply with Paragraph 10e, below;
 - (7) Remain accountable for those responsibilities which they delegate;

- (8) Develop and implement a quality assurance program governing the work of their organization in accordance with the requirements of Paragraph 9, as applicable;
 - (9) Designate an individual or individuals to be responsible for bringing the following to the attention of the Department's Contracting Officer: (a) each procurement requiring the application of this Order, (b) requirements for flow down of provisions of this Order to any subcontract or sub-award, and (c) identification of the parts of this Order with which the contractor or subcontractor is to comply. Unless another individual is designated, the responsibility is that of the Procurement Request Originator (the individual responsible for initiating a requirement of DOE F 4200.33). Contracting Officers, based on the advice of the Procurement Request Originator or other designated individual. Shall apply applicable provisions of this Order to awards falling within its scope.
 - (10) Ensure that appropriate attention is given to the weapons component and production facility interface, where applicable.
- b. Assistant Secretary for Nuclear Energy (NE-1), in addition to the responsibilities prescribed in subparagraph 10a, has overall responsibility for developing and coordinating Departmental policy for nuclear reactors and non-reactor nuclear facility safety. The Assistant Secretary for Nuclear Energy has the following additional responsibilities:
- (1) Develop, promulgate, and maintain quality assurance policy for DOE nuclear work;
 - (2) Provide advice and assistance to PSOs concerning implementation of this Order;
 - (3) In concert with EH-1, provide a central point for coordination within DOE and liaison with other agencies and groups in the development of quality assurance policy, standards, guidance, and requirements; and
 - (4) Review proposed statutes (where appropriate), regulations, standards, and requirements for their application to and potential impact on DOE programs;
- c. Director of the Office of Nuclear Safety (NS-1), acting as the Department's independent element responsible for nuclear safety oversight, has the following responsibilities:
- (1) Assess and report to the Secretary of Energy on all aspects of nuclear safety related to the implementation of this order, including the performance of the Program Offices, Field Offices, and contractors; and

- (2) Review proposed quality assurance policy, regulations, standards, and requirements to assess their potential effects on the nuclear safety of DOE facilities.
- d. Assistant Secretary for Environment, Safety and Health (EH-1), acting as DOE's independent element responsible for oversight of worker health and safety (including radiation protection), environmental protection, and safeguards and security, has the following responsibilities in addition to those prescribed in subparagraph 10a:
- (1) Develop, promulgate, and maintain quality assurance policy for DOE non-nuclear work;
 - (2) Develop, promulgate, and maintain quality assurance policy for environmental compliance and data collection activities that is consistent with the guidelines established by the Environmental Protection Agency's Quality Assurance Management Staff office;
 - (3) Provide advice and assistance to PSOs concerning implementation of this order;
 - (4) In concert with NE-1, provide a central point of contact for coordination with DOE and liaison with other agencies and groups in the development of quality assurance policy, standards, guidance, and requirements;
 - (5) Review proposed statutes (where appropriate), regulations, standards, and requirements for their application to and potential impact on DOE programs; and
 - (6) Assess non-nuclear work to monitor implementation of this order.
- e. DOE Field Office Managers have the following responsibilities:
- (1) As directed by the Lead PSO, ensure the adequacy and implementation of contractors' quality assurance programs by performing independent assessments in accordance with Paragraph 9b(3)(b). Coordinate work with, and utilize resources of, other cognizant DOE organizations, as appropriate; and
 - (2) Develop and implement a quality assurance program governing the work of the Field Office in accordance with the requirements of Paragraph 9, as applicable. Submit the program to the Lead PSO for approval.
- f. Administrators of the Power Marketing Administrations: Section 302 of the DOE Organization Act (PL 95-91) directs the Secretary to operate and maintain the Power Marketing Administrations by and through their Administrators. The Administrators have the statutory and public utility responsibilities for the safety, security, and reliability of the systems operated by their organizations. The Administrators shall review and approve the quality assurance standards, policies, and activities appropriate for their facilities and operations. Such determination shall include appropriate consideration of the criteria set forth in this Order.

g. Director of the Naval Propulsion Program: Executive Order 12344, statutorily prescribed by P.L. 98-525 (42 U.S.C. 7158, note) establishes the responsibilities and authority of the Director, Naval Nuclear Propulsion Program (who is also the Deputy Assistant Secretary for Naval Reactors within the Department) for all facilities and work which comprise the Program, a joint Navy-DOE organization. These executive and legislative actions establish the responsibilities of the Director as including the safety of reactors and associated naval nuclear propulsion plants, the control of radiation and radioactivity associated with naval nuclear propulsion plants, and the operating practices and procedures applicable to naval nuclear propulsion plants. Accordingly, the provisions of this order do not apply to the Naval Nuclear Propulsion Program. The Director shall establish the quality assurance requirements implemented within the program.

11. INTERPRETATIONS. Requests for interpretation of the requirements of this Order shall be forwarded for action, together with proposed resolutions, to NE-1 for nuclear work and to EH-1 for non-nuclear work.

BY ORDER OF THE SECRETARY OF ENERGY:

JOHN J. NETTLES, JR.
Director of Administration
and Human Resource Management

QUALITY ASSURANCE PROGRAM
IMPLEMENTATION GUIDE

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GUIDANCE FOR DEVELOPING AND IMPLEMENTING QUALITY ASSURANCE PROGRAMS

I. Introduction.

This document provides guidance for developing and implementing Quality Assurance Programs (QAPs) that satisfy the requirements of DOE 5700.6C. It also specifies the criteria to be used by DOE to review and approve Field Offices' and contractor s' QAPs. The guidance depicts contemporary principles and techniques for managing, achieving, and assessing quality. Other techniques may be used to meet the quality assurance criteria in Paragraph 9b, providing the DOE Lead Program Secretarial Officer (PSO) concurs.

This guide reflects current quality principles and practices, and it uses concepts and terms that have evolved through experience. Quality is the degree to which an item or process meets or exceeds the user's requirements and expectations. Quality assurance constitutes those actions which when carried out provide confidence that quality is achieved. The goal of DOE is to instill a culture in which there is a commitment to achieve a rising standard of quality. This culture demands that process and item quality and the methods employed to achieve quality be continuously improved.

The guidance provided herein reflects the concept that all work is a process that can be planned, performed, assessed, and improved. This guide provides the Department's interpretation of the ten criteria which comprise the foundation of a comprehensive quality assurance program. The criteria are broken down into three functional categories: Management, Performance, and Assessment. These categories capture the range of activities common to all work, from organizing and staffing to assessing results and providing feedback to improve the process. Within the three functional categories are the quality assurance criteria that provide the basic requirements of a quality assurance program. The application of these criteria extends from the planning and conduct of basic research and development, scientific investigation, and engineering design to operations, maintenance and repair, and eventual environmental restoration. As such, these quality assurance criteria reflect a comprehensive way of doing business throughout the life cycle of DOE programs and projects.

The principles and practices embodied in this guide apply to all aspects of work. It is the role of senior management to establish and cultivate principles that integrate quality requirements into daily work. Senior management should provide individuals performing the work the proper information, tools, support, and encouragement to properly perform their assigned work. Senior management should define requirements; properly train, motivate, and empower personnel; provide appropriate resources; and assess performance. Senior management is expected to demonstrate commitment and leadership to achieve quality through active involvement in the implementation of an effective quality assurance program. The individuals role is to meet the quality requirements while recommending improvements in item and process quality.

In structuring the organization and assigning responsibilities, quality assurance should be recognized as an interdisciplinary function involving many organizational components and should not be regarded as the sole domain of any single quality assurance group. Achieving quality is the responsibility of people throughout the organization, from the top executives to workers, including designers, scientists, engineers, welders, inspectors, researchers, operators, craftsmen, and auditors.

Some quality assurance programs developed using existing standards or guides may require modification to address the requirements of DOE 5700.6C. Programs developed and properly implemented using ASME/NQA-1 will meet the majority of the requirements of this Order. For programs which are not based on ASME/NQA-1, other standards and guidance may be used to supplement this document. Organizations should use each standard or guidance document in combination with DOE 5700.6C to ensure their programs address the applicable requirements. The format and number of criteria contained in an organization's QAP are important only if they affect the organization's performance.

II. Guidance.

Risk is the fundamental consideration in determining to what extent the QAP should be applied to items and processes. Risk is a quantitative and/or qualitative expression of possible loss which considers both the probability of event occurrence causing harm or loss and the consequences of that event. Criteria, such as consequences of failure, probability of failure, data generation function, complexity or uniqueness of design or fabrication, special controls, ability to demonstrate functional compliance, quality history, degree of standardization, impact on the environment, and impact on schedule or cost or both should be considered in determining risk. Organizations should use proven risk-related information of both qualitative and quantitative nature where available. Organizations should be cautioned to not use risk analysis to mitigate the importance of accomplishing work (e.g., equipment maintenance) which, when not performed, tends to have a long term negative affect on the achievement of the organization's objectives. Risk-related information includes current Safety Analysis Reports (SAR's), accident analyses, environmental impact reports, probabilistic risk assessments (PRAs), operating safety reviews, or other appropriate studies and information.

The intent of DOE 5700.6C is that Quality Assurance Programs be developed individually for large scale and unique operations, as well as similar work which shares common management and objectives. DOE facilities, such as national scientific and engineering laboratories, contain many diverse operations and may be expected to have a combination of large scale or unique operations and facilities revolving around one area of research. Because of the unique nature of some organizations' work, not all quality assurance criteria will always apply. In those cases where an organization believes certain criteria or parts of criteria do not apply to their work, the Lead PSO must concur.

Guidance for developing and using the 10 quality assurance criteria is as follows:

A. Management.

1. Criterion 1--Program.

- a. Senior management should develop and issue a written quality assurance policy statement which commits the organization to implement a formal Quality Assurance Program (QAP).
- b. Senior Management should retain and exercise the responsibility for the scope and implementation of an effective QAP. Line management is responsible for the achievement of quality. Each individual is responsible for the quality of his/her work.
- c. The QAP should promote effective and efficient achievement of performance objectives.
- d. The QAP should be binding on all personnel, including those having responsibility for planning and scheduling. Management should take the necessary actions to ensure that the QAP is understood and implemented.
- e. The quality of items and processes should be ensured to an extent consistent with their risk.
- f. The QAP should describe or provide reference to organizational structure, functional responsibilities, levels of authority, and interfaces. The description should include the onsite and offsite organizational elements that function within the scope of the QAP. The organization should establish criteria for developing individual QAPs or combining similar work under a single QAP when appropriate. Functional responsibilities include work such as planning; training and personnel development; preparing, reviewing, approving, and verifying designs; qualifying suppliers; preparing, reviewing approving, and issuing instructions, procedures, schedules, and procurement documents; purchasing; verifying supplier work; identifying and controlling hardware and software; manufacturing; managing and operating facilities; calibrating and controlling measuring and test equipment; conducting investigations and acquiring data; performing maintenance, repair, and improvements; performing assessments; and controlling records.
- g. A common vocabulary that is consistent and representative of the work being performed should be adopted. Key terminology should be defined. Personnel

indoctrination should include appropriate definitions to ensure consistent understanding and communication.

- h. Work assigned to parties outside the organization should be identified. For assigned work, management controls should be established, responsibilities assigned, and lines of communication identified.
- i. Initial estimates, used in planning, should be based on sound data and assumptions relating to personnel, material/service costs, availabilities, and productivity.
- j. Readiness reviews should be performed prior to a major scheduled or planned work and should be performed to verify at least the following characteristics:
 - 1) Work prerequisites have been satisfied;
 - 2) Detailed technical and QA procedures have been reviewed for adequacy and appropriateness;
 - 3) Personnel have been suitably trained and qualified; and
 - 4) The proper equipment, material, and resources are available.
- k. Responsibility and authority to stop unsatisfactory work should be assigned such that planning and schedule considerations do not override safety considerations. A readiness review in accordance with A.I.j. above should be performed prior to restarting work.

2. Criterion 2--Personnel Training and Qualification.

- a. Personnel performing work should be capable of performing their assigned tasks. Qualification requirements should be established for specific job categories, such as operators, designers, managers, supervisors, inspectors, welders, engineers, scientists, and independent assessment personnel. Training includes both education in principles and enhancement of skills and practices. Training should ensure the worker understands the processes and tools he/she is using, the extent and sources of variability in those processes and tools, and the degree to which he/she does and does not have control over that variability.
- b. Training should emphasize correct performance of work and provide understanding of why quality requirements exist. In addition, training should provide an understanding of the fundamentals of the work and its context. Training instruction should address potential consequences of improper work

and focus attention on "doing it right the first time."

- c. Training plans should address and stimulate professional development. Training plans should provide for maintenance of proficiency and progressive improvement, and should not be limited to attainment of initial qualification. Training plans for management personnel should include professional, managerial, communication, and interpersonal skills.
- d. Personnel performing work that requires special skills or abilities should be qualified prior to performing work. Qualification should include demonstrated proficiency of each candidate and periodically thereafter to maintain skills to meet current practices.
- e. Training should provide curricula that address specific needs, and it should be presented by qualified instructors.
- f. Training should be subject to on-going review to determine program and instruction effectiveness. Training and qualification should be upgraded whenever needed improvements or other enhancements are identified.

3. Criterion 3--Quality Improvement.

- a. Processes should be established and implemented with the objective of preventing problems and improving quality. Examples of planning and problem prevention include but are not limited to peer reviews, design reviews, probabilistic risk assessments, safety analysis reports, and reliability/availability/ maintainability analyses. The focus of quality improvement should be to reduce the variability of every process which influences the quality of the product.
- b. Performance data, internal and external failure costs, prevention costs, and other quality-related information should be analyzed to identify trends that adversely impact quality and to identify opportunities to improve items and processes. Examples of such information include increasing process capability studies which define assignable and inherent causes of process variability, failure rates, increasing corrective maintenance, and decreasing preventive maintenance resources. To identify commonalities, the analysis should consider information from external sources and not be limited to one type of work, one facility, or one contractor.
- c. Processes should be established and implemented to promote continuous improvement. This includes the identification and improvement of expected performance standards and associated performance measures.

- d. All personnel should identify nonconforming items and processes. All personnel should be encouraged by management to identify and suggest improvements. All personnel should be granted the freedom and authority to stop work until effective corrective action is taken.
- e. Items and processes that do not meet established requirements, goals, or do not result in the anticipated quality should be promptly identified, documented, analyzed, resolved, and followed up. The extent of cause analyses for nonconforming items and processes should be commensurate with-the importance or significance of the problem.
- f. Management, at all levels, should foster a no-fault attitude to encourage the identification of nonconforming items and processes. Management should be involved in the quality improvement process to ensure that proper focus is given, adequate resources are allocated and difficult issues are resolved. A process for resolving professional differences of views and opinions should be established and implemented.
- g. Nonconforming items and processes should be properly controlled to prevent their inadvertent test, installation, or use. They should be reviewed by the organization that originally reviewed and approved the items or processes or a designated organization that is qualified and knowledgeable. The justification for disposition should be appropriately documented.
- h. Reworked, repaired, and replacement items and processes should be inspected and tested in accordance with original requirements or specified alternatives.
- i. Personnel responsible for analyzing and dispositioning nonconformances should have an adequate technical understanding of the area in which they are working and have access to pertinent background information relative to the nonconformance.

4. Criterion 4--Documents and Records.

- a. Documents.
 - (1) A process should be established and implemented to control preparation, review, approval, issuance, use, and revision of documents that establish policies. prescribe work, specify requirements, or establish design.
 - (2) The scope of the document control system should be defined. Examples of documents to be controlled include drawings, data files (including various

media), calculations, specifications, computer codes, purchase orders and related documents, vendor-supplied documents, procedures, work instructions, operator aids, and data sheets.

- (3) Revisions to controlled documents should be reviewed and approved by the organization that originally reviewed and approved the documents. An alternative organization may be designated based on technical competence and capability. Timeliness guidelines should be implemented for distribution of new or revised controlled documents.
- (4) Controlled documents should be distributed to and used by personnel performing work.
- (5) Control of superseded and canceled documents should include measures to ensure that only correct documents are in use. Record copies should be marked "superseded or canceled" and kept for a specified retention period.

b. Records.

- (1) A process should be established and implemented to ensure that sufficient records (for example, records of design, environmental conditions, applied research and development, procurement, construction, data acquisition, assessments, inspection, testing, maintenance, and modification) are specified, prepared, reviewed, approved, and maintained to accurately reflect completed work. The maintenance of records should include provisions for retention, protection, preservation, traceability, accountability, and retrievability.
- (2) For records that require special processing and control, such as computer codes or information on high density media or optical disks, hardware and software required to maintain and access records should be controlled to ensure records are usable.
- (3) Records holding facilities are reserved for storage of inactive records and may not meet the physical requirements or have appropriate staff to maintain active records. Active records requiring special handling, storage, and processing should not be sent to records holding facilities. Users should refer to the General Records Schedule (GRS) or DOE 1324.2A for retention and disposition of records.

- (4) The National Archives and Records Administration (NARA) exercises final authority for approving the disposition of Government records. Use of the GRS, which is published by the NARA, and the DOE unique schedules approved by the NARA are mandatory.
- (5) Some standards which provide interpretive quality assurance guidance may differ in records management terminology from the NARA requirements. In those instances, care should be taken to ensure that the requirements of both the NARA and standards are followed.

B. Performance.

1. Criterion 5--Work Processes.

a. Work.

- (1) Personnel performing work are responsible for the quality of their work. Because the individual worker is the first line in ensuring quality, personnel should be knowledgeable of requirements for work they perform and the capability of the tools and processes they use.
- (2) Line managers should ensure that personnel work under their supervision are provided the necessary training, resources, and administrative controls to accomplish assigned tasks. Criteria describing acceptable work performance should be defined for the worker.
- (3) Line managers should review work and related information to ensure that the desired quality is being achieved and to identify areas needing improvement.
- (4) Work should be planned, authorized, and accomplished under controlled conditions using technical standards, instructions, procedures, or other appropriate means of a detail commensurate with the complexity and risk of the work.
- (5) Work-related instructions, procedures, and other forms of direction should be developed, verified, validated, and approved by technically competent personnel.

b. Identification and Control of Items.

- (1) Processes should be established and implemented to identify, control, and maintain items.
- (2) Identification of items should be maintained to ensure appropriate traceability
- (3) Processes should be established and implemented to control consumables and items with limited shelf life, prevent the use of incorrect or defective items, and control samples.

c. Handling, Storing, and Shipping.

- (1) A process should be established and implemented to control the handling, storage, shipping, cleaning, and preservation of items to prevent damage, loss, or deterioration.
- (2) Marking and labeling of items should be maintained throughout packaging, shipping, handling, and storage. Marking and labeling should provide information to identify items and provide instructions or special controls to preserve items' integrity. Requirements for offsite transportation should be established and implemented.
- (3) Special protective measures (such as containers, shock absorbers, accelerometers, inert gas atmospheres, and specific temperature and moisture levels) should be specified and provided when required to maintain acceptable quality.

d. Calibration and Maintenance of Monitoring and Data Collection Equipment.

- (1) A process should be established and implemented to control the calibration, maintenance, and use of measuring and test equipment used for monitoring and data collection.
- (2) Monitoring and data collection equipment should be of the accuracy and type suitable for the intended use. The types of equipment included should be specified. Equipment should have calibration certifications traceable to national standards, where possible.

2. Criterion 6--Design.

- a. A process should be established and implemented for design using sound engineering/scientific principles and appropriate standards, such as the General Design Criteria (DOE 6430.1A). Provisions should include control of design requirements, inputs, processes, outputs, changes, records, and organizational interfaces.
- b. Design input, such as the design bases, reliability requirements, and fire protection requirements, should be correctly translated into design output, such as specifications, drawings, procedures, and instructions.
- c. Changes to final designs, field changes, modifications, and nonconforming items dispositioned use as is" or repair" should be justified and subject to design control measures commensurate with the original design. This work should include assurance that the design analyses for the items are still valid. Changes should be approved by the original design organization or a technically qualified designate.
- d. Design interfaces should be identified and controlled and design efforts should be coordinated among and within participating organizations. Interface controls should include the assignment of responsibility and establishment of procedures among participating design organizations.
- e. Design records, maintained to provide evidence that the design was properly accomplished, should include not only the final design output and its revision, but also important design steps (calculations, analyses, and computer programs, for example) and sources of input that support final output.
- f. The acceptability of design work and documents, including design inputs, processes, outputs, and changes, should be verified. Computer programs should be proven through previous use, or validated through testing or simulation prior to use.
- g. Design verification should be performed by qualified individual(s) or groups(s) other than those who performed the original design - but who may be from the same organization. The extent of verification should be based on the complexity, risk, and uniqueness of the design.
- h. Verification methods include, but are not limited to, design reviews, alternate calculations, and qualification testing. Separate verification may not be needed for multiple uses of identical or previously proven designs, unless they are intended for different applications or different performance criteria

- i. Testing to verify or validate acceptability of a specific design feature should demonstrate acceptable performance under conditions that simulate the most adverse design conditions. Operating or test modes and environmental conditions in which items must perform satisfactorily should be considered in determining the most adverse conditions.
- j. Design verification should be completed before design output is used by other organizations or to support other work, such as procurement, manufacture, construction, or experiment. When this timing cannot be achieved, the unverified portion of the design should be identified and controlled'. In all cases, design verifications should be completed before relying on the item to perform its function and before installation becomes irreversible (requiring extensive demolition or rework).

3. Criterion 7--Procurement.

- a. A process should be established and implemented to ensure that purchased items and services meet established requirements and perform as expected.
- b. Applicable technical and administrative requirements, such as specifications, codes, standards, tests, and inspections should be invoked for procurement of items and services. Procurement documents should include acceptance criteria.
- c. Appropriate controls for the selection, determination of suitability, evaluation, and receipt of all purchased items, including commercial-grade items, should be imposed to ensure that they perform as expected.
- d. Prospective suppliers should be evaluated to ensure that only qualified suppliers are selected.
- e. Qualified suppliers and, as necessary, sub-tier suppliers should be monitored periodically to ensure that acceptable items and services continue to be supplied.
- f. Purchased items and services should be accepted using specified methods (such as review of manufacturing process control data, source verification, receipt inspection, pre-installation and post-installation tests, certificates of conformance, or a combination of these methods).
- g. Before a procured item is used or placed in service, procurement specification, inspection, and test requirements are to be satisfied and nonconformances properly dispositioned.

- h. The actual performance of items should be compared with original performance criteria. User group surveys, supplier evaluations, inspection and test results, and performance data should be reviewed to determine procurement effectiveness.
- i. The quality of purchased items and services should be verified at intervals to a degree consistent with the item's or service's complexity, risk, quantity, and frequency of procurement.
- j. In cases where there are indications that suppliers knowingly supplied items and services of substandard quality, this information should be forwarded to the DOE Office of Inspector General.

4. Criterion 8 - Inspection and Acceptance Testing.

a. Inspection.

- (1) A process should be established and implemented to specify when and what type of inspections (source, in- process, final, receipt, maintenance, and in-service, for example) are required. Administrative controls and status indicators should be used to preclude inadvertent bypassing of required inspections and to prevent inadvertent operation of the item or process.
- (2) Inspections may be implemented by or for the organization performing the work to be inspected. Personnel may not inspect their own work for acceptance. The level of inspection and degree of independence of inspection personnel should be based on risk and complexity.
- (3) Provisions to ensure inspection planning is properly accomplished should be established. Planning should identify item characteristics and processes to be inspected, inspection techniques, acceptance criteria, hold points, and the organization responsible for performing inspection.
- (4) When acceptance criteria are not met, deficiencies should be resolved and reinspection should occur as required.

b. Acceptance Testing.

- (1) Testing processes should be established and implemented to demonstrate that items and processes will perform as intended. Testing should include, as appropriate, bench tests and proof tests before installation,

pre-operational tests, post-maintenance tests, post-modification tests, and operational tests. Testing should be structured so that proving designs should not be confused with proofing the adequacy of work.

- (2) Testing may be implemented by or for the organization performing the work to be tested. When an organization performs its own testing, personnel with the organization should not test their own work for acceptance.
- (3) Item and process test requirements and acceptance criteria should be provided by or approved by the organization responsible for design. Administrative controls and status indicators should be used to preclude inadvertent bypassing of required tests or operation of the item or process.
- (4) Test procedures should be developed and include:
 - (a) instructions and prerequisites to perform the test;
 - (b) completeness and accuracy of data;
 - (c) use of test equipment;
 - (d) acceptance criteria;
 - (e) inspection hold points as required; and
 - (f) test article configuration.
- (5) Retesting of items or processes to determine that they meet acceptance criteria is required after deficiencies are corrected.

c. Measuring and Test Equipment.

- (1) A process should be established and implemented to control calibration, maintenance, accountability, and use of equipment used to control any process parameter which influences the quality of an item's characteristics, or which is used for in-process or final inspection of an item.
- (2) The types of equipment to be used, such as instruments, tools, gages, reference and transfer standards, and nondestructive examination equipment should be defined.

- (3) Measuring and test equipment should be calibrated at specified intervals, or immediately before and after use, on the basis of the item's required accuracy, intended use, frequency of use, stability characteristics, and other conditions affecting its performance.
- (4) Measuring and test equipment should be labeled, tagged, or otherwise controlled to indicate its calibration status and ensure traceability to calibration test data.
- (5) Measuring and test equipment should be Calibrated against standards having an accuracy that will ensure that equipment being calibrated will be within required tolerances. If nationally recognized standards exist, calibration standards should be traceable to such standards.
- (6) Measuring and test equipment found out-of-calibration or out-of-tolerance should be tagged or segregated and not used until it is successfully recalibrated. The acceptability of items or processes measured, inspected, or tested with an out-of-tolerance device should be determined.

C. Assessment.

1. Criterion 9 - Management Assessment.

- a. Planned and periodic management assessments should be established and implemented as a way to improve quality. Management assessments should focus on how well the integrated quality assurance program is working and should identify management problems that hinder the organization from achieving its objectives in accordance with quality, safety, and environmental requirements.
- b. Senior management should retain overall responsibility for management assessments. Direct participation by senior management during management assessments is essential. This process should involve all levels of management, as appropriate.
- c. Management assessment results should be documented. Senior management should take prompt action and document resulting decisions in response to recommendations resulting from the management assessment process. Follow-up should include an evaluation of the effectiveness of management's actions.

2. Criterion 10 - Independent Assessment.

- a. A process of planned and periodic independent assessments should be established and implemented by an independent assessment organization. Independent assessments should focus on improving items and processes by emphasizing line organization's achievement of quality.
- b. Personnel performing independent assessments should act in a management advisory function. Their responsibilities are to monitor work performance, identify abnormal performance and precursors of potential problems, identify opportunities for improvement, report results to a level of management having the authority to effect corrective action, and verify satisfactory resolution of problems.
- c. Personnel performing independent assessments should be technically knowledgeable and focus on improving the quality of the processes that lead to the end product.
- d. Personnel performing independent assessments should not have direct responsibilities in the area they are assessing.
- e. Independent assessments should be conducted using criteria that describe acceptable work performance and promote improvement.
- f. Scheduling of assessments and allocation of resources should be based on the status, risk, and complexity of the item or process being assessed. Scheduling should be flexible and additional attention should be given to areas of questionable performance.
- g. Assessment results should be tracked and resolved by management having responsibility in the area assessed. Follow up review of deficient areas should be initiated as necessary.
- h. Responses to assessments should include the following, as applicable: action to correct the deficiency; cause identification; actions to prevent recurrence; lesson learned; and actions to be taken for improvement.